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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1618]

Draft "Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis'' dated December 2000. The draft guidance document provides recommendations to blood establishments that wish to distribute blood and blood components collected from individuals with diagnosed hereditary hemochromatosis without indicating the donor's disease on the container label, or collect blood more frequently than every 8 weeks without a physical examination and certification of the donor's health by a physician on the day of donation. This draft guidance document identifies the conditions under which FDA will consider approving the above as alternative procedures, or variances, to the current regulations, and provides guidance on what to submit when requesting these variances. These recommendations apply to all blood establishments, whether or not they hold a U.S. License for the manufacture of blood and blood components.

DATES: Submit written comments on the draft guidance to ensure their adequate consideration in preparation of the final document by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written requests for single copies of ''Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis'' dated December 2000, to

the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biological Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The document may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800, or by fax by calling the FAX Information system at 1–888–CBER–FAX or 301–827–3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance document entitled ''Guidance for Industry: Variances for Blood Collection from Individuals with Hereditary Hemochromatosis'' dated December 2000. This document identifies the conditions under which FDA will consider approving the above as alternative procedures, or variances, to the current regulations, under the provisions of 21 CFR 640.120 and provides guidance on what to submit when requesting these variances.

On April 29, 1999, the Public Health Service Advisory Committee on Blood Safety and Availability (ACBSA) recommended that the Department of Health and Human Services (DHHS) ''create policies that eliminate incentives to seek [blood] donation for purposes of phlebotomy'' from patients with diagnosed hemochromatosis who require phlebotomy as therapy for their disease. Further, as undue incentives to donate blood for transfusion (rather than being therapeutically

phlebotomized) are removed, DHHS ''should create policies that eliminate barriers to using this resource'' to augment the country's blood supply (Ref. 1).

On August 10, 1999, the Commissioner of Food and Drugs made a commitment to consider case-by-case exemptions to existing blood labeling and donor suitability regulations for blood establishments that can verify that therapeutic phlebotomy for hemochromatosis is performed at no expense to the patient (Ref. 2). FDA additionally committed itself to work with the Health Care Financing Administration in ensuring that the financial incentives for persons with hereditary hemochromatosis (HH) to donate blood for transfusion are removed. This issue was further discussed at the FDA Blood Products Advisory Committee meeting on September 16, 1999 (Ref. 3). The statutory authority and scope of jurisdiction of HCFA limits its ability to reduce or eliminate costs of treatment for HH patients, many of whom are covered by private insurers, or do not have health insurance. Thus, for the foreseeable future, if blood centers wish to distribute blood collected from donors with HH without disease labeling, they will have the responsibility of removing financial incentives for these donors. Each blood center will have to evaluate the advantages of entering these donors into their donor pool.

The draft guidance document is being issued consistent with the final rule on good guidance practices (21 CFR 10.15; 65 FR 56468, September 19, 2000). The draft guidance document represents the agency's current thinking on blood collection from individuals with hereditary hemochromatosis. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. References

The following have been placed on display in the Dockets Management Branch and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Nightingale, S. D., Summary of Advisory Committee Meeting of April 29 and 30, 1999. May 13, 1999. http://www.hhs.gov/partner/bloodsafety/04–99sum.html

2. Henney, J. E., Memorandum Blood Donations by Individuals with Hemo chromatosis, August 10, 1999. http://www.hhs.gov/partner/bloodsafety/JEH8–10jpg

3. Blood Products Advisory Committee, 64th Meeting, September 16, 1999. http://www.fda.gov/ohrms/dockets/ac/cber99.htm-Blood Products Advisory Committee

III. Comments

The draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance document. Submit written comments to ensure adequate consideration in preparation of the final document by [*insert date 90 days after date of publication in the* **Federal Register**]. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cber/guidelines.htm.

Dated: 11-28-00
November 28, 2000

Margaret M. Dotzel
Associate Commissioner for Policy

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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